

AMENDED IN SENATE JANUARY 6, 2005

SENATE BILL

No. 19

Introduced by Senator Ortiz
(Principal coauthor: Senator Poochigian)

December 6, 2004

An act to add Division ~~113~~ 112 (commencing with Section 130600) to the Health and Safety Code, relating to ~~prescription drugs~~ *pharmacy assistance*, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter ~~in to~~ into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Program, to be ~~administered by~~ *Pharmacy Assistance Program (Cal Rx) under the oversight of the department*. The bill would authorize the department to *implement and administer Cal Rx through a contract with a 3rd-party vendor or utilizing existing health care service provider enrollment and payment mechanisms*. The bill would require the department or 3rd-party vendor to attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers to ~~provide for program drug discounts~~. The bill would authorize any licensed pharmacy ~~or and any drug manufacturer, as defined,~~ to provide services under ~~the program~~ *Cal Rx*. The bill would establish eligibility criteria and application procedures for California residents to participate in ~~the program~~ *Cal Rx*. The application process would

require an applicant to attest to information provided under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. The bill would authorize the department to terminate the program if any one of 3 determinations are made .

The bill would establish the California Rx— State Pharmacy Assistance Program Fund , as a continuously appropriated fund, into which all payments directly received under the program— Cal Rx would be deposited. The bill would continuously appropriate the fund to the department for purposes of Cal Rx.

The bill would appropriate \$3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.

The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.

This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: ~~no~~.

The people of the State of California do enact as follows:

- 1 ~~SECTION 1. Division 113 (commencing with Section~~
- 2 ~~130600) is added to the Health and Safety Code, to read:~~
- 3 ~~SECTION 1. Division 112 (commencing with Section~~
- 4 ~~130600) is added to the Health and Safety Code, to read:~~

*DIVISION 112. CALIFORNIA STATE PHARMACY
ASSISTANCE PROGRAM (CAL RX)*

CHAPTER 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

1 (g) “Manufacturer” means a drug manufacturer as defined in
2 Section 4033 of the Business and Professions Code.

3 (h) “Manufacturers rebate” means the rebate for an
4 individual drug or aggregate rebate for a group of drugs
5 necessary to make the price for the drug ingredients equal to or
6 less than the applicable benchmark price.

7 (i) “Prescription drug” means any drug that bears the
8 legend: “Caution: federal law prohibits dispensing without
9 prescription,” “Rx only,” or words of similar import.

10 (j) “Private discount drug program” means a prescription
11 drug discount card or manufacturer patient assistance program
12 that provides discounted or free drugs to eligible individuals. For
13 the purposes of this division, a private discount drug program is
14 not considered insurance or a third-party payer program.

15 (k) “Recipient” means a resident that has completed an
16 application and has been determined eligible for Cal Rx.

17 (l) “Resident” means a California resident pursuant to
18 Section 17014 of the Revenue and Taxation Code.

19 (m) “Third-party vendor” means a public or private entity
20 with whom the department contracts pursuant to subdivision (b)
21 of Section 130602, which may include a pharmacy benefit
22 administration or pharmacy benefit management company.

23 130602. (a) There is hereby established the California
24 State Pharmacy Assistance Program or Cal Rx.

25 (b) The department shall provide oversight of Cal Rx. To
26 implement and administer Cal Rx, the department may contract
27 with a third-party vendor or utilize existing health care service
28 provider enrollment and payment mechanisms, including the
29 Medi-Cal program’s fiscal intermediary.

30 (c) Any resident may enroll in Cal Rx if determined eligible
31 pursuant to Section 130605.

32
33 CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS
34

35 130605. (a) To be eligible for Cal Rx, an individual shall
36 meet all of the following requirements at the time of application
37 and reapplication for the program:

38 (1) Be a resident.

39 (2) Have family income, as reported pursuant to Section
40 130606, that does not exceed 300 percent of the federal poverty

1 *guidelines, as revised annually by the United States Department*
 2 *of Health and Human Services in accordance with Section 673(2)*
 3 *of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C.*
 4 *Sec. 9902), as amended.*

5 *(3) Not have outpatient prescription drug coverage paid for in*
 6 *whole or in part by any of the following:*

7 *(A) A third-party payer.*

8 *(B) The Medi-Cal program.*

9 *(C) The children's health insurance program.*

10 *(D) The disability medical assistance program.*

11 *(E) Another health plan or pharmacy assistance program that*
 12 *uses state or federal funds to pay part or all of the cost of the*
 13 *individual's outpatient prescription drugs. Notwithstanding any*
 14 *other provision of this division to the contrary, an individual*
 15 *enrolled in Medicare may participate in this program, to the*
 16 *extent allowed by federal law, for prescription drugs not covered*
 17 *by Medicare.*

18 *(4) Not have had outpatient prescription drug coverage*
 19 *specified in paragraph (3) during any of the three months*
 20 *preceding the month in which the application or reapplication*
 21 *for Cal Rx is made, unless any of the following applies:*

22 *(A) The third-party payer that paid all or part of the*
 23 *coverage filed for bankruptcy under the federal bankruptcy laws.*

24 *(B) The individual is no longer eligible for coverage provided*
 25 *through a retirement plan subject to protection under the*
 26 *Employee Retirement Income Security Act of 1974 (29 U.S.C.*
 27 *Sec. 1001), as amended.*

28 *(C) The individual is no longer eligible for the Medi-Cal*
 29 *program, children's health insurance program, or disability*
 30 *medical assistance program.*

31 *(b) Application and an annual reapplication for Cal Rx shall*
 32 *be made pursuant to subdivision (d) of Section 130606. An*
 33 *applicant, or a guardian or custodian of an applicant, may apply*
 34 *or reapply on behalf of the applicant and the applicant's spouse*
 35 *and children.*

36 *130606. (a) The department or third-party vendor shall*
 37 *develop an application and reapplication form for the*
 38 *determination of a resident's eligibility for Cal Rx.*

39 *(b) The application, at a minimum, shall do all of the*
 40 *following:*

1 (1) Specify the information that an applicant or the
2 applicant's representative must include in the application.

3 (2) Require that the applicant, or the applicant's guardian or
4 custodian, attest that the information provided in the application
5 is accurate to the best knowledge and belief of the applicant or
6 the applicant's guardian or custodian.

7 (3) Include a statement printed in bold letters informing the
8 applicant that knowingly making a false statement is punishable
9 under penalty of perjury.

10 (4) Specify that the application and annual reapplication fee
11 due upon submission of the applicable form is fifteen dollars
12 (\$15).

13 (c) In assessing the income requirement for Cal Rx eligibility,
14 the department shall use the income information reported on the
15 application and not require additional documentation.

16 (d) Application and annual reapplication may be made at any
17 pharmacy, physician office, or clinic participating in Cal Rx,
18 through a Web site or call center staffed by trained operators
19 approved by the department, or through the third-party vendor.
20 A pharmacy, physician office, clinic, or third-party vendor
21 completing the application shall keep the application fee as
22 reimbursement for its processing costs. If it is determined that the
23 applicant is already enrolled in Cal Rx, the fee shall be returned
24 to the applicant and the applicant shall be informed of his or her
25 current status as a recipient.

26 (e) The department or third-party vendor shall utilize a
27 secure electronic application process that can be used by a
28 pharmacy, physician office, or clinic, by a Web site, by a call
29 center staffed by trained operators, or through the third-party
30 vendor to enroll applicants in Cal Rx.

31 (f) During normal hours, the department or third-party
32 vendor shall make a determination of eligibility within four hours
33 of receipt by Cal Rx of a completed application. The department
34 or third-party vendor shall mail the recipient an identification
35 card no later than four days after eligibility has been determined.

36 (g) For applications submitted through a pharmacy, the
37 department or third-party vendor may issue a recipient
38 identification number for eligible applicants to the pharmacy for
39 immediate access to Cal Rx.

1 130607. (a) The department or third-party vendor shall
2 attempt to execute agreements with private discount drug
3 programs to provide a single point of entry for eligibility
4 determination and claims processing for drugs available in those
5 private discount drug programs.

6 (b) (1) Private discount drug programs may require an
7 applicant to provide additional information, beyond that
8 required by Cal Rx, to determine the applicant's eligibility for
9 discount drug programs.

10 (2) An applicant shall not be, under any circumstances,
11 required to participate in, or to disclose information that would
12 determine the applicant's eligibility to participate in, private
13 discount drug programs in order to participate in Cal Rx.

14 (3) Notwithstanding paragraph (2), an applicant may
15 voluntarily disclose or provide information that may be
16 necessary to determine eligibility for participation in a private
17 drug discount program.

18 (c) For those drugs available pursuant to subdivision (a), the
19 department or third-party vendor shall develop a system that
20 provides a recipient with the best prescription drug discounts
21 that are available to them through Cal Rx or through private
22 discount drug programs.

23 (d) The recipient identification card issued pursuant to
24 subdivision (g) of Section 130606 shall serve as a single point of
25 entry for drugs available pursuant to subdivision (a) and shall
26 meet all legal requirements for a uniform prescription drug card
27 pursuant to Section 1363.03.

28 29 CHAPTER 3. ADMINISTRATION AND SCOPE 30

31 130615. (a) To the extent that funds are available, the
32 department shall conduct outreach programs to inform residents
33 about Cal Rx and private drug discount programs available
34 through the single point of entry as specified in subdivisions (a)
35 and (d) of Section 130607. No outreach material shall contain
36 the name or likeness of a drug. The name of the organization
37 sponsoring the material pursuant to subdivision (b) may appear
38 on the material once and in a font no larger than 10 point.

39 (b) The department may accept on behalf of the state any gift,
40 bequest, or donation of outreach services or materials to inform

1 residents about Cal Rx. Neither Section 11005 of the Government
2 Code, nor any other law requiring approval by a state officer of
3 a gift, bequest, or donation shall apply to these gifts, bequests, or
4 donations. For purposes of this section, outreach services may
5 include, but shall not be limited to, coordinating and
6 implementing outreach efforts and plans. Outreach materials
7 may include, but shall not be limited to, brochures, pamphlets,
8 fliers, posters, advertisements, and other promotional items.

9 (c) An advertisement provided as a gift, bequest, or donation
10 pursuant to this section shall be exempt from Article 5
11 (commencing with Section 11080) of Chapter 1 of Part 1 of
12 Division 3 of Title 2 of the Government Code.

13 130616. (a) Any pharmacy licensed pursuant to Article 7
14 (commencing with Section 4110) of Chapter 9 of Division 2 of
15 the Business and Professions Code may participate in Cal Rx.

16 (b) Any manufacturer, as defined in subdivision (g) of Section
17 130601, may participate in Cal Rx.

18 130617. (a) This division shall apply only to prescription
19 drugs dispensed to noninpatient recipients.

20 (b) The amount a recipient pays for a drug within Cal Rx
21 shall be equal to the pharmacy contract rate pursuant to
22 subdivision (c), plus a dispensing fee that shall be negotiated as
23 part of the rate pursuant to subdivision (c), less the applicable
24 manufacturers rebate.

25 (c) The department or third-party vendor may contract with
26 participating pharmacies for a rate other than the pharmacist's
27 usual and customary rate. However, the department must
28 approve the contracted rate of a third-party vendor.

29 (d) The department or third-party vendor shall provide a
30 claims processing system that complies with all of the following
31 requirements:

32 (1) Charges a price that meets the requirements of
33 subdivision (b).

34 (2) Provides the pharmacy with the dollar amount of the
35 discount to be returned to the pharmacy.

36 (3) Provides a single point of entry for access to private
37 discount drug programs pursuant to Section 130607.

38 (4) Provides drug utilization review warnings to pharmacies
39 consistent with the drug utilization review standards outlined in

1 *Section 1927 of the federal Social Security Act (42 U.S.C. Sec.*
2 *1396r-8(g)).*

3 *(e) The department or third-party vendor shall pay a*
4 *participating pharmacy the discount provided to recipients*
5 *pursuant to subdivision (b) by a date that is not later than two*
6 *weeks after the claim is received.*

7 *(f) The department or third-party vendor shall develop a*
8 *program to prevent the occurrence of fraud in Cal Rx.*

9 *(g) The department or third-party vendor shall develop a*
10 *mechanism for recipients to report problems or complaints*
11 *regarding Cal Rx.*

12 *130618. (a) In order to secure the discount required*
13 *pursuant to subdivisions (b) and (c) of Section 130617, the*
14 *department or third-party vendor shall attempt to negotiate drug*
15 *rebate agreements for Cal Rx with drug manufacturers.*

16 *(b) Each drug rebate agreement shall do all of the following:*

17 *(1) Specify which of the manufacturer's drugs are included in*
18 *the agreement.*

19 *(2) Permit the department to remove a drug from the*
20 *agreement in the event of a dispute over the drug's utilization.*

21 *(3) Require the manufacturer to make a rebate payment to the*
22 *department for each drug specified under paragraph (1)*
23 *dispensed to a recipient.*

24 *(4) Require the rebate payment for a drug to be equal to the*
25 *amount determined by multiplying the applicable per unit rebate*
26 *by the number of units dispensed.*

27 *(5) Define a unit, for purposes of the agreement, in*
28 *compliance with the standards set by the National Council of*
29 *Prescription Drug Programs.*

30 *(6) Require the manufacturer to make the rebate payments to*
31 *the department on at least a quarterly basis.*

32 *(7) Require the manufacturer to provide, upon the request of*
33 *the department, documentation to validate that the per unit*
34 *rebate provided complies with paragraph (4).*

35 *(8) Permit a manufacturer to audit claims for the drugs the*
36 *manufacturer provides under Cal Rx. Claims information*
37 *provided to manufacturers shall comply with all federal and state*
38 *privacy laws that protect a recipient's health information.*

39 *(c) To obtain the most favorable discounts, the department*
40 *may limit the number of drugs available within Cal Rx.*

1 (d) The entire amount of the drug rebates negotiated pursuant
2 to this section shall go to reducing the cost to Cal Rx recipients
3 of purchasing drugs. The Legislature shall annually appropriate
4 an amount to cover the state's share of the discount provided by
5 this section.

6 (e) The department or third-party vendor may collect
7 prospective rebates from manufacturers for payment to
8 pharmacies. The amount of the prospective rebate shall be
9 contained in drug rebate agreements executed pursuant to this
10 section.

11 (f) Drug rebate contracts negotiated by the third-party
12 vendor shall be subject to review by the department. The
13 department may cancel a contract that it finds not in the best
14 interests of the state or Cal Rx recipients.

15 (g) The third-party vendor may directly collect rebates from
16 manufacturers in order to facilitate the payment to pharmacies
17 pursuant to subdivision (e) of Section 130617. The department
18 shall develop a system to prevent diversion of funds collected by
19 the third-party vendor.

20 130619. (a) The department or third-party vendor shall
21 generate a monthly report that, at a minimum, provides all of the
22 following:

- 23 (1) Drug utilization information.
- 24 (2) Amounts paid to pharmacies.
- 25 (3) Amounts of rebates collected from manufacturers.
- 26 (4) A Summary of the problems or complaints reported
27 regarding Cal Rx.

28 (b) Information provided in paragraphs (1), (2), and (3) of
29 subdivision (a) shall be at the national drug code level.

30 130620. (a) The department or third-party vendor shall
31 deposit all payments received pursuant to Section 130618 into
32 the California State Pharmacy Assistance Program Fund, which
33 is hereby established in the State Treasury.

34 (b) Notwithstanding Section 13340 of the Government Code,
35 moneys in the fund are hereby appropriated to the department
36 without regard to fiscal years for the purpose of providing
37 payment to participating pharmacies pursuant to Section 130617
38 and for defraying the costs of administering Cal Rx.
39 Notwithstanding any other provision of law, no money in the fund

1 *is available for expenditure for any other purpose or for loaning*
2 *or transferring to any other fund, including the General Fund.*

3 *130621. The department may hire any staff needed for the*
4 *implementation and oversight of Cal Rx.*

5 *130622. The department shall seek and obtain confirmation*
6 *from the federal Centers for Medicare and Medicaid Services*
7 *that Cal Rx complies with the requirements for a state*
8 *pharmaceutical assistance program pursuant to Section 1927 of*
9 *the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that*
10 *discounts provided under the program are exempt from Medicaid*
11 *best price requirements.*

12 *130623. (a) Contracts and change orders entered into*
13 *pursuant to this division and any project or systems development*
14 *notice shall be exempt from all of the following:*

15 *(1) The competitive bidding requirements of State*
16 *Administrative Manual Management Memo 03–10.*

17 *(2) Part 2 (commencing with Section 10100) of Division 2 of*
18 *the Public Contract Code.*

19 *(3) Article 4 (commencing with Section 19130) of Chapter 5*
20 *of Part 2 of Division 5 of the Government Code.*

21 *(b) Change orders entered into pursuant to this division shall*
22 *not require a contract amendment.*

23 *130624. The department may terminate Cal Rx if the*
24 *department makes any one of the following determinations:*

25 *(a) That there are insufficient discounts to participants to*
26 *make Cal Rx viable.*

27 *(b) That there are an insufficient number of applicants for Cal*
28 *Rx.*

29 *(c) That the department is unable to find a responsible*
30 *third-party vendor to administer Cal Rx.*

31 *130625. Notwithstanding Chapter 3.5 (commencing with*
32 *Section 11340) of Part 1 of Division 3 of Title 2 of the*
33 *Government Code, the director may implement this division in*
34 *whole or in part, by means of a provider bulletin or other similar*
35 *instructions, without taking regulatory action.*

36 *SEC. 2. No reimbursement is required by this act pursuant*
37 *to Section 6 of Article XIII B of the California Constitution*
38 *because the only costs that may be incurred by a local agency or*
39 *school district will be incurred because this act creates a new*
40 *crime or infraction, eliminates a crime or infraction, or changes*

1 *the penalty for a crime or infraction, within the meaning of*
2 *Section 17556 of the Government Code, or changes the definition*
3 *of a crime within the meaning of Section 6 of Article XIII B of the*
4 *California Constitution.*

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6
7 **All matter omitted in this version of the bill**
8 **appears in the bill as introduced in Senate,**
9 **December 6, 2004 (JR11)**
10